



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[CMS-3434-FN]**

### **Medicare and Medicaid Programs: Application from the Accreditation Commission for Health Care, Inc. for Continued Approval of its End-Stage Renal Disease (ESRD) Accreditation Program**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This final notice announces our decision to approve the Accreditation Commission for Health Care, Inc for continued recognition as a national accrediting organization for end stage renal disease facilities that wish to participate in the Medicare or Medicaid programs.

**DATES:** The decision announced in this final notice is applicable on April 11, 2023 through April 10, 2029.

#### **FOR FURTHER INFORMATION CONTACT:**

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#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Under the Medicare program, eligible beneficiaries may receive covered services from an end stage renal disease (ESRD) facility provided certain requirements are met. Section 1881(b) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as an ESRD facility. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR

part 488. The regulations at 42 CFR part 494 specify the minimum conditions that an ESRD facility must meet to participate in the Medicare program.

Generally, to enter into an agreement, an ESRD facility must first be certified by a state survey agency (SA) as complying with the conditions or requirements set forth in part 494 of our regulations. Thereafter, the ESRD facility is subject to regular surveys by a SA to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS)-approved national accrediting organization (AO) that all applicable Medicare requirements are met or exceeded, we will deem those provider entities as having met such requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at §§488.4, 488.5 and 488.5(e)(2)(i). The regulations at §488.5(e)(2)(i) require AOs to reapply for continued approval of its accreditation program every 6 years or sooner, as determined by CMS.

ACHC's current term of approval for their ESRD facility accreditation program expires April 11, 2023.

## **II. Application Approval Process**

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner.

The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

### **III. Provisions of the Proposed Notice**

On October 4, 2022, we published a proposed notice in the **Federal Register** (87 FR 60171), announcing ACHC's request for continued approval of its Medicare ESRD facility accreditation program. In the October 4, 2022 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at §488.5, we conducted a review of ACHC's Medicare ESRD facility accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- A virtual onsite administrative review of ACHC's: (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its ESRD surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ESRD facilities; and (5) survey review and decision-making process for accreditation.

- The comparison of ACHC's Medicare ESRD facility accreditation program standards to our current Medicare ESRD facility conditions of participation (CoPs).

- A documentation review of ACHC's survey process to do the following:

- ++ Determine the composition of the survey team, surveyor qualifications, and ACHC's ability to provide continuing surveyor training.

++ Compare ACHC's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against ACHC accredited ESRD facilities.

++ Evaluate ACHC's procedures for monitoring accredited ESRD facilities it has found to be out of compliance with ACHC's program requirements. (This pertains only to monitoring procedures when ACHC identifies non-compliance. If noncompliance is identified by a SA through a validation survey, the SA monitors corrections as specified at §488.9(c)).

++ Assess ACHC's ability to report deficiencies to the surveyed ESRD facilities and respond to the ESRD facilities' plans of correction in a timely manner.

++ Establish ACHC's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of ACHC's staff and other resources.

++ Confirm ACHC's ability to provide adequate funding for performing required surveys.

++ Confirm ACHC's policies with respect to surveys being unannounced.

++ Confirm ACHC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain ACHC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

#### **IV. Analysis of and Responses to Public Comments on the Proposed Notice**

In accordance with section 1865(a)(3)(A) of the Act, the October 4, 2022 proposed notice also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare CoPs for ESRD facilities. No comments were received in response to our proposed notice.

## **V. Provisions of the Final Notice**

### **A. Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements**

We compared ACHC's ESRD facility accreditation requirements and survey process with the Medicare CoPs of parts 494, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of ACHC's ESRD facility accreditation application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this final notice, ACHC has completed revising its standards and certification processes in order to--

- Meet the standard's requirements of all of the following regulations:

- ++ Section 494.30(b)(3)(x), to clarify and address the contingency plans for staff who are not fully vaccinated for COVID-19.

- ++ Section 494.60(d)(1), to address dialysis facilities that do not provide one or more exits to the outside must comply with Life Safety Code (NFPA 101).

- ++ Section 494.60(d)(4), to clarify specific Life Safety Code provisions that may be waived, only if the waiver will not adversely affect the health and safety of the patients.

- ++ Section 494.60(d)(5), to clarify that no dialysis facility may operate in a building adjacent to an industrial high hazard area.

In addition to the standards review, CMS also reviewed ACHC's comparable survey processes, which were conducted as described in section III. of this final notice, and yielded the following areas where, as of the date of this final notice, ACHC has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

- ++ Revising the compliant policies and processes to align with the State Operations Manual, Chapter 5 guidance. In particular, the Administrative Review Offsite Investigation

process to align with the triage process to track and trend for potential focus areas during the next onsite survey or complete an onsite complaint investigation.

++ Clarifying the quantifying data surrounding equipment and maintenance logs, specifically the equipment review. The survey reports or notes need to identify the number of logs reviewed, date or timeframes.

++ Providing surveyor training on documentation reviews and the process for verifying the completeness of the facility request.

++ Reinforcing and providing education to facility surveyors to request Dialysis Facility Reports, the reports provide aggregate data regarding laboratory values, demographic information, mortality rates, hospitalizations, infections, etc., which may assist the surveyors during the review of patient medical records.

++ Developing additional surveyor training for verifying all elements required for the CMS emergency preparedness requirements.

#### B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve ACHC as a national accreditation organization for ESRD facilities that request participation in the Medicare program. The decision announced in this final notice is effective April 11, 2023 through April 11, 2029 (6 years). In accordance with §488.5(e)(2)(i) the term of the approval will not exceed 6 years.

While ACHC has taken actions based on the findings annotated in section V.A., of this final notice, (Differences Between ACHC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements) as authorized under §488.8, we will continue ongoing review of ACHC's ESRD survey substance and processes. In keeping with CMS's initiative to increase AO oversight broadly, and ensure that our requested revisions by ACHC are completed, CMS expects more frequent review of ACHC's activities in the future.

## **VI. Collection of Information Requirements**

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: March 15, 2023.

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**Evell J. Barco Holland,**

Federal Register Liaison,

Center for Medicare & Medicaid Services.